

**Section II (Remarks)****A. Summary of Amendment to the Claims**

Claim 1 has been amended as set forth in the above Complete Listing of the Claims.

As amended, the claims are supported by the specification and the original claims and do not add new matter, as defined by 35 U.S.C. § 132. Specifically the amendment of claim 1 is supported by Example 1 as detailed in the discussion presented under Heading “B. Rejection Under 35 U.S.C. §112” below.

The amendments do not require a new search, or raise new issues for consideration because they merely address issues already raised by the examiner or define applicants’ invention more clearly.

It is submitted that the amendments place the claims in condition for allowance or in better condition for appeal by reducing the number of issues for consideration on appeal. The amendments were not made earlier in the prosecution because it is maintained that the previously pending claims were allowable.

Since the amendments do not add new matter or require a new search or consideration, and place the claims in condition for allowance or in better condition for appeal, entry of the amendment is respectfully requested.

Thus, upon entry of the amendments, claims 1, 6, 7, and 9-13 remain pending and under examination.

**B. Rejections Under 35 U.S.C. §112****Written Description**

In the Office Action mailed November 3, 2011, the examiner rejected claims 1, 6, 7, and 9-13 under 35 U.S.C. §112, first paragraph as lacking written description.

It is well established that “[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.” (MPEP 2163, citing *Moba*,

*B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.)

The examiner asserted that recitation of the terms “*fadL* gene (GenBank Accession No. U00096)” and “the C terminal end (nucleotides 1156-1347) of the *fadL* gene” are not supported by the specification. Applicants respectfully disagree.

It is well established that in satisfying the written description requirement of 35 U.S.C. §112 “[w]hat is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.” (MPEP 2163)

In the Response filed August 24, 2011, it was noted that the sequence of the *fadL* gene is well known in the art and is deposited GenBank Accession No. U00096. A printout of GenBank Accession No. U00096 was provided as Exhibit A.

Furthermore, Exhibit B, providing a copy of the Cristalli, et al. article was provided to show that it was well known in the art that nucleotides 1156-1347 of the *fadL* gene are positioned on the ninth loop of the *fadL* gene.

Therefore the amendment of claim 1 to include recitation of “*fadL* gene (GenBank Accession No. U00096)” and “the C terminal end (nucleotides 1156-1347) of the *fadL* gene” was supported by the knowledge of those of skill in the art.

However, in order to advance prosecution of the present application, claim 1 has been amended herein such that it no longer contains recitation of either “GenBank Accession No. U00096” or “the C terminal end...of the *fadL* gene.” As amended, claim 1 recites in relevant part “...a *fadL* gene encoding an *E. coli* outer membrane protein (FadL) in which nucleotides 1156-1347 of the *fadL* gene have been removed...” Such language is fully supported by Example 1 of the specification, at pages 13-14 the specification.

One of skill in the art would have reasonably concluded from Example 1 that the inventors had possession of the claimed invention. The full *fadL* gene, deposited GenBank Accession No. U00096, as provided as Exhibit A to the Response mailed August 24, 2011, is known to one of skill in the art. By the description provided in Example 1, the first 385 amino acids (nucleotides 1-1155) of the FadL protein were obtained by PCR using the primers of SEQ ID NOs 1 and 2.

From the known *fadL* gene sequence and the primer sequences provided on page 13 of the application, one of skill in the art would reasonably conclude that applicants were in possession of the following sequence:

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gaatc
atgGTCAATGA  GCCAGAAAAAC  CCTGTAAACA  AAGTCTGCTC  TCGCAGTCGC  AGTGGCACTT
ATCTCCACCC  AGGCCTGGTC  GGCAGGCTTT  CAGTTAACG  AATTTCTTC  CTCTGGCTG
GGCCGGGCTT  ATTCAGGGGA  AGCGCAATT  GCCGATGATG  CAGGTAAACGT  CAGCCGTAAC
CCCGCATTGA  TTACTATGTT  TGACCGCCCC  ACATTTCTG  CGGGTGCCTT  TTATAATTGAC
CCGGATGTA  ATATCAGCGG  AACGTCTCCA  TCTGGTCGTA  GCCTGAAAGC  CGATAACATC
GCCGCTACGG  CATGGGTTCC  GAACATGCAC  TTTGTGCAAC  CGATTAACGA  CCAATTGGT
TGGGGCGCTT  CTATTACCTC  TAACTATGGT  CTGGCTACAG  AGTTAACGA  TACTTATGCA
GGCGGCTCTG  TCGGGGGTAC  AACCGACCTT  GAAACCATGA  ACCTGAACTT  AAGCGGTGCG
TATCGCTTAA  ATAATGCATG  GAGCTTGGT  CTTGGTTCA  ACCCGCTCTA  CGCTCGCCG
AAAATTGAAC  GTTTCGCAGG  CGATCTGGGG  CAGTTGGTG  CTGGCCAAAT  TATGCAATCT
CCTGCTGGCC  AAACTCAGCA  AGGGCAAGCA  TTGGCAGCTA  CCGCCAACGG  TATTGACAGT
AATACCAAAA  TCGCTCATCT  GAACGTAAC  CAGTGGGGCT  TTGGCTGGAA  CGCCGGAATC
CTGTATGAA  TGATAAAAAA  TAACCGCTAT  GCACTGACCT  ACCGTTCTGA  AGTGAAAATT
GACTTCAAAG  GTAACTACAG  CACCGATCTT  AATCGTGGT  TTAATAACTA  CGGTTTGCCTA
ATTCCCTACCG  CGACAGGTGG  CGCAACGCAA  TCGGGTTATC  TGACGCTGAA  CCTGCCCTGAA
ATGTGGGAAG  TGTCAAGGTTA  TAACCGTGT  GATCCACAGT  GGGCGATTCA  CTATAGCCTG
GCTTACACCA  GCTGGAGTCA  GTTCCAGCAG  CTGAAAGCGA  CCTCAACCCAG  TGGCGACACG
CTGTTCCAGA  AACATGAAGG  CTTAAAGAT  GCTTACCGCA  TCGCGTTGGG  TACCACTTAT
TACTACGATG  ATAATCTGGAC  CTTCCTGTACC  GGTATCGCT  TTGATGACAG  CCCAGTTCT
GCACAGAAC  GTTCT agagc

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Such sequence comprises nucleotides 1-1155 and “agagc.”

Therefore truncation of nucleotides 1156-1347 would be clear to one of skill in the art as the “C-terminal” end of the *fadL* gene.

Furthermore, the sequences were cloned into plasmid pTrc99A at the *EcoRI* and *XbaI* sites to make pTrcFadL, as recited at page 14 and illustrated in Figure 1. The last part of the sequence, the “gc” base pair, was deleted by the *EcoRI* and *XbaI* restriction enzymes. Accordingly, an arginine (aga) was inserted at the C terminus by introduction at the *XbaI* cleavage site, at the 3’ end of the truncated *fadL* gene encoding the first 385 amino acids:

CGT	TCT	<b>aga</b>
arginine	serine	arginine

From the specification it would have been clear to one of skill in the art that the applicants were in possession of “...a *fadL* gene encoding an *E. coli* outer membrane protein (FadL) in which nucleotides 1156-1347 of the *fadL* gene have been removed...” from the disclosure of Example 1, demonstrating a truncated *fadL* gene encoding an *E. coli* outer membrane protein (FadL)

in which nucleotides 1156-1347 of the *fadL* gene (GenBank Accession No. U00096) were removed.

Additionally, provided herewith in Exhibit A is a publication by the inventors of the present application, published subsequent to the priority filing of the present application. In the publication it is seen that the inventors described a similar experiment in which primers 1 and 2 in Table 1 (page 5075) were used to amplify “truncated *fadL*,” as fully described at page 5076, in the paragraph spanning column 1-column 2:

“...[t]he truncated *fadL* (*fadL<sub>t</sub>*) gene encoding the first 384 amino acids from the N terminus was amplified by PCR using primers 1 and 2 and was cloned into the EcoRI and XbaI sites of pTrc99A to make pTrcFadL ...[o]ne arginine was additionally inserted at the C terminus by introducing the baI site at the 3' end of the *fadL<sub>t</sub>* gene.”

Claim 1, and claims 6, 7 and 9-13 dependent therefrom, therefore comply with the written description requirement of 35 U.S.C. §112, first paragraph and withdrawal of the rejection is respectfully requested.

### **Definiteness**

In the Office Action mailed November 3, 2011, the examiner has rejected claim 1 and dependent claims 6, 7 and 9-13 under 35 U.S.C. §112, second paragraph as indefinite.

In the Office Action, the examiner rejected independent claim 1 for recitation of both broad and narrow definitions of the same element. Specifically the examiner rejected recitation of both “a *fadL* gene” and “GenBank Accession No. U00096” and also recitation of “the C terminal end” and “nucleotides 1156-1347.”

In order to address the issue raised by the examiner, the claim has been amended to recite in relevant part “...a *fadL* gene encoding an *E. coli* outer membrane protein (FadL) in which nucleotides 1156-1347 of the *fadL* gene have been removed...” Recitation of “GenBank Accession No. U00096” and “the C terminal end” have been removed from the claim.

As amended, claims 1 is in compliance with the requirements of 35 U.S.C. § 112, second paragraph. Withdrawal of the rejection is respectfully requested.

**CONCLUSION**

Based on the foregoing, all of applicants' pending claims 1, 6, 7, and 9-13 are patentably distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing and to responsively issue a Notice of Allowance.

No fees are believed to be due for the filing of this paper. However, should any fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any issues require further resolution, the examiner is requested to contact the undersigned attorneys at (919) 419-9350 to discuss same.

Respectfully submitted,

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**Encl:**  
**Exhibit A [7 pgs.]**

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